

# Evaluation of vascular hemodynamics in alveolar bone post exodonty in vivo through experimental endoscopic imagenology: pilot study

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<b>Registration date</b> 08/09/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/09/2019	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Endoscopy has seen significant development over recent years in various medical fields with its application expanding from the support of minimal invasive surgery to in situ imaging. In this context, the application of endoscopic techniques to assess the quality of the regenerated bone in situ in the drill hole before implant placement is an appealing approach. The aim of this study is to use short distance support immersion endoscopy (SD-SIE) to compare the quality of regenerated bone in healed post-extraction sites, which are grafted with an in situ hardening  $\beta$ -TCP, against un-grafted sites, before implant placement. This assessment is based on microscopic bone analysis in combination with the blood vessel count.

### Who can participate?

Two groups of patients with ages ranging from 18 to 85, including male and female patients, with native bone (extraction performed without graft material) and regenerated bone (extraction performed with graft material four to six months before the implantation), evaluated at the time of implant cavity preparation

### What does the study involve?

Implant sites are assessed using SD-SIE, including blood vessels, mineralised area, non-mineralised area and the amount of resting bone substitute.

### What are the possible benefits and risks of participating?

Endoscopic observation allows the detection of possible intraoperative accidents during implant preparation such as bone wall perforation, accidental contact with neurovascular structures and detection of foreign objects. Associated risks during the surgery are the same as with any tooth extraction such as pain and bleeding after the surgery and allergy against the anaesthesia.

### Where is the study run from?

Implant Clinic of the Dental School of Universidad de La Frontera, Temuco (Chile)

When is the study starting and how long is it expected to run for?

March 2017 to October 2018

Who is funding the study?

The study was supported with biomaterials from Sunstar Suisse SA, Etoy, Switzerland to the Universidad de La Frontera, Temuco, Chile. Universidad de La Frontera also funded the study via a grant (DIUFRO No. DI17-0170)

Who is the main contact?

Prof. Dr. Víctor Beltrán

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

DIUFRO project N° DI17-0170

## Study information

### Scientific Title

In situ endoscopic analysis of vascular supply and regenerated alveolar bone in  $\beta$ -TCP grafted and un-grafted post extraction sites before implant placement: a prospective case-control study

### Study objectives

The aim of this study was to use short distance support immersion endoscopy (SD-SIE) to compare the quality of regenerated bone in healed post-extraction sites, which are grafted with an in situ hardening  $\beta$ -TCP, against un-grafted sites, before implant placement. This assessment was based on microscopic bone analysis in combination with the blood vessel count.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 15/03/2017, Universidad de La Frontera Ethics Committee (Postal address: 4780000; Tel: +56 (0)452325775; Email: cec@ufrontera.cl), Decision 118/16

## **Study design**

Pilot prospective case-control study

## **Primary study design**

Observational

## **Secondary study design**

Case-control study

## **Study setting(s)**

Hospital

## **Study type(s)**

Diagnostic

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Dental implant in mandibular or maxillary sites

## **Interventions**

A total of 13 grafted and 13 un-grafted alveolar sites were analyzed with short distance support immersion endoscopy (SD-SIE) in the drill hole right before implant placement. The sites belonged to the anterior maxillary zone including premolars, canines and incisors. All participants' data were anonymized to ensure confidentiality and the grafted and un-grafted groups were randomized for a blind analysis.

Vessels, mineralized and unmineralized zones are measured before implant placement by support immersion endoscopy (SD-SIE) to compare the quality of regenerated bone and healing in post-extraction sites.

The assessment is made based on microscopic bone analysis (SD-SIE) in combination with blood vessel count according to the following protocol: (1) Selection of the area of interest (AoI), (2) Screenshot of images after irrigation and cleaning, (3) Set of the scale bar according to the transversal diameter of the scope window (contact mode) at the center of the image and definition of the area of measurement using Image J software.

Vessels are identified by observing the original video recordings that were recorded by the endoscopic procedure in vivo after cleaning the bone surface with saline solution. The percentages were calculated from area of mm<sup>2</sup> by: Unmineralized bone or vessels multiplied by 100 and then divided by the Area of Interest (AoI). The mineralized bone area is calculated from the difference of the AoI from the vessels area selected plus non-mineralized bone. Bright white areas are selected as Bone Substitute. Vessels are counted in a blinded manner. Sites with

pulsatile extravasation from arterial vessels were excluded, if the Aoi could not be cleansed sufficiently.

### **Intervention Type**

Other

### **Primary outcome measure**

The implant sites were evaluated using SD-SIE after 4-6 months. SD-SIE was applied in drill holes before implant placement, and videos were taken from representative central buccal areas. Measured at a single timepoint.

### **Secondary outcome measures**

Video recordings analyzed using Image J software for:

1. Number of blood vessels per area (NBV)
2. Relative area of vessels (VA)
3. Relative area of mineralized bone (MBA)
4. Relative area of unmineralized bone (UMBA)
5. Relative area of bone substitute (BSA)

Measured at a single timepoint

### **Overall study start date**

15/03/2017

### **Completion date**

01/10/2018

## **Eligibility**

### **Key inclusion criteria**

1. Patients older than 18 years old
2. Total or partial dentition
3. Indication for a dental implant in adequately formed mandibular or maxillary sites without regenerated bone
4. Indication of a dental implant in mandibular or maxillary sites, previously regenerated

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

Minimal 8 patients

**Key exclusion criteria**

1. Drug abuse
2. Systemic diseases
3. Purulent local inflammation
4. Severe cardiovascular diseases
5. Active orthodontic treatment
6. Heavy smokers (>10 cigarettes/day)

**Date of first enrolment**

15/05/2017

**Date of final enrolment**

01/05/2018

**Locations****Countries of recruitment**

Chile

**Study participating centre**

The Implant Clinic of the Dental School of Universidad de la Frontera (UFRO)

Claro Solar 115

Temuco

Chile

4780000

**Sponsor information****Organisation**

Universidad de La Frontera, Temuco, Chile (DIUFRO project N° DI17-0170)

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**Sponsor type**

University/education

**Website**

<http://cec.ufro.cl/>

ROR

<https://ror.org/04v0snf24>

## Funder(s)

### Funder type

Industry

### Funder Name

The study was supported with biomaterial from Sunstar Suisse SA, Etoy, Switzerland (DIUFRO-DI17-0170)

## Results and Publications

### Publication and dissemination plan

BioMed Research International. The special issue: "Biomechanical Properties of Biomaterials /Scaffolds for Bone Tissue Regeneration"

### Intention to publish date

01/12/2019

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dr Víctor Beltrán ([victor.beltran@ufrontera.cl](mailto:victor.beltran@ufrontera.cl)), Prof. Dr Wilfried Engelke ([wengelke@med.uni-goettingen.de](mailto:wengelke@med.uni-goettingen.de)) and Dr Márcio Lazzarini ([lazzarini@em.mpg.de](mailto:lazzarini@em.mpg.de)).

### IPD sharing plan summary

Available on request